MAR 2 2 2005

K050037

II. 510(k) Summary of Safety and Effectiveness

Triage® TOX Drug Screen Controls

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: (To be determined)

A. Name and Address of Submitter

Company Name:	Biosite Incorporated
Address:	11030 Roselle Street San Diego, CA 92121
Telephone:	(858) 455-4808
Fax:	(858) 535-8350
Contact Person:	Jeffrey R. Dahlen, Ph.D.
Date Summary Prepared:	1/6/2005

B. Device Names

1. Trade Name

   Triage® TOX Drug Screen Controls

2. Common / Usual Name

   Not Applicable

3. Classification Name

   Quality Control Material (Assayed and Unassayed)
   21 CFR 862:3280
   Class I
   Product Code: DIF

C. Predicate Devices

Triage TOX Drug Screen Controls (K012999)
BIO-RAD Liquicheck Urine Toxicology Controls (K981590, K970666)
Dade Behring Emit Calibrators/Controls (K935230)

D. Device Description and Intended Use

The Triage TOX Drug Screen Controls are to be used with the Triage TOX Drug Screen tests and Triage MeterPlus to assist the laboratory in monitoring test performance.

E. Summary of Comparison Data

The table below provides a comparison of the technical principles between the Triage TOX Drug Screen Controls and the predicate devices.

Characteristic	Triage TOX Drug Screen Controls	Bio-Rad Liquicheck	Dade Behring Emit
Intended Use	Assayed control for monitoring urine-based drugs of abuse assays	Assayed control for monitoring urine-based drugs of abuse assays	Assayed control for monitoring urine-based drugs of abuse assays
Matrix	Human Urine	Human Urine	Human Urine
Form	Liquid	Liquid	Liquid
Analytes	Commonly abused drugs	Commonly abused drugs	Commonly abused drugs
Storage	-20 °C or colder	2-8 °C	2-8 °C

F. Conclusion

The information provided in the premarket notification demonstrates that the Triage TOX Drug Screen Controls are substantially equivalent to previously approved predicate devices. The information provided assures that the Triage TOX Drug Screen Controls are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 2 2005

Jeffrey R. Dahlen, Ph.D
Director, Clinical & Regulatory Affairs
Biosite Inc.
11030 Roselle Street
San Diego, CA 92121

Re: K050037
Trade Name: Triage TOX Drug Screen Controls
Regulatory Number: 21 CFR 862.3280
Regulatory Name: Clinical toxicology control material
Regulatory Class: Class I
Product Code: DIF
Dated: February 18, 2005
Received: February 22, 2005

Dear Dr. Dahlen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050037

Device Name: Triage TOX Drug Screen Controls

Indications For Use:

The Triage TOX Drug Screen Controls are to be used with the Triage TOX Drug Screen tests and Triage MeterPlus to assist the laboratory in monitoring test performance.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K050037